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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/399,083	09/17/1999	DAVID CALDERWOOD	BBIC-043/A	1842

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EXAMINER

RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

MAIL DATE	DELIVERY MODE
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04/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/399,083	CALDERWOOD ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,10,11 and 48-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 10-11, 48-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This office action is in response to the amendment filed on January 22, 2009.

Claims 1-6, 8, 10-11 and 48-51 are pending in this application.

Withdrawn Rejections/Objections:

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

The obviousness-type double patenting rejection over U.S. 6,660,744 of the previous office action is withdrawn. The reference claims are drawn to pyrazolo-pyrimidine compounds as compared to the instantly claimed compounds which are drawn to pyrrolo-pyrimidine compounds.

Election/Restrictions

The amendment filed January 22, 2009 amends claim 1 by narrowing the definition of "Ring A" with the deletion of the recitation 'a six membered aromatic ring'. Accordingly, the prior art rejection over WO 98/41525 is rendered moot in view of the claim amendments.

As per the instructions of MPEP § 803.02, the search and examination is expanded to the entire scope of the claimed invention. Previously withdrawn claims 48-51 have been rejoined and examined together.

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The following rejections are maintained:

Claims 1-6, 8, 10-11 and 48-51 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-63 of U.S. Patent No. 6,713,474. The reasons provided in the previous office action are incorporated here by reference.

Applicant's request to hold the rejection in abeyance until allowable claims are found in the application is acknowledged.

The following rejections are under new grounds:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8, 10, and 48-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compound represented by formula depicted in claim 1 wherein ring A is a five or six membered heteroaromatic ring and L is an independent group (as defined in page 3), does not reasonably provide enablement for a compound of the formula (as shown in claim 1) wherein "L is $-R_bN(R)S(O)_2-$, $-R_bN(R)P(O)-$, or $-R_bN(R)P(O)O-$, wherein R_b is an alkylene group which when taken together with the sulphonamide, phosphinamide, or phosphonamide group to which it is bound forms a five or six membered ring fused to ring A". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed. The determination that “undue experimentation” would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations.

The specification fails to enable the preparation of the entire scope of the claimed compounds. The instant claims recited that:

L is $-R_bN(R)S(O)_2-$, $-R_bN(R)P(O)-$, or $-R_bN(R)P(O)O-$, wherein R_b is an alkylene group which when taken together with the sulphonamide, phosphinamide, or phosphonamide group to which it is bound forms a five or six membered ring fused to ring A; or

The specification, however, does not provide any explanation of such “fused” heterocyclic rings. The process schemes 1-4 in pages 60-70 of the specification provide the essential starting materials to prepare the claimed compounds of formula (depicted in claim 1) wherein Ring A is a phenyl or a monocyclic five or six membered heteroaromatic ring and L is an independent linear linking group described in the claims, however, there is no disclosure of the sources of starting materials needed to prepare for compounds wherein L is $-R_bN(R)S(O)_2-$, $-R_bN(R)P(O)-$, or $-R_bN(R)P(O)O-$, wherein R_b is an alkylene group which when taken together with the sulphonamide, phosphinamide, or phosphonamide group to which it is bound forms a five or six membered ring fused to ring A. The specification does not provide any explanation or sources of

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such compounds, such that a person of ordinary skill could prepare compounds with instantly recited structural features.

The specification does not provide any explanation or sources of starting materials or the resulting products wherein 'L is $-R_bN(R)S(O)_2-$, $-R_bN(R)P(O)-$, or $-R_bN(R)P(O)O-$, wherein R_b is an alkylene group which when taken together with the sulphonamide, phosphinamide, or phosphonamide group to which it is bound forms a five or six membered ring fused to ring A', such that a person of ordinary skill could determine which groups are suitable to prepare the instantly claimed compounds. For example, if one R_b represents a group alkylene and along with the amino-sulfonyl to which it is attached, then the fused cyclic group formed by L and ring A together will have completely different structural features, which are not described in the schemes nor in the examples. The resulting compounds will have a very complex heterocyclic group which is neither explained nor illustrated in the specification. The specification does not sufficiently describe synthetic procedures with the necessary starting compounds and reagents to prepare such embodiments encompassed by the instant claims; nor such embodiments are illustrated via examples.

In view of the lack of direction provided in the specification regarding starting materials, the lack of working examples and the general unpredictability of chemical reactions, it would take an undue amount of experimentation for one skilled in the art to make the claimed compounds and therefore practice the invention. The starting material sources necessary to obtain the instant compounds must have been available as of the filing date in order to provide an enabling disclosure. See *In re Howarth*, 654 F.2d 103, 210 USPQ 689 (CCPA 1981); *Ex parte*

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Moersch, 104 USPQ 122 (POBA 1954). Applicants should show that the sources of these starting materials was common knowledge or readily available at the time of filing.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 11 and 48-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. Claim 6 recites the limitation "ring A is substituted with one or more substituents selected from the group consisting of CN, **CO₂CH₃**, ... **carboxyl**, ..." in lines 1-7. There is insufficient antecedent basis for this limitation in claim 1 on which claim 6 is dependent (via claim 5). The list of substituents for ring A provided in claim 1 does not include a carboxyl or a methyl ester (i.e., CO₂CH₃) group. Further, claim 6 recites that "ring A is substituted with ... **-S-(substituted or unsubstituted aryl)**,", which again is not identically listed in claim 1. Claim 1 contains the recitation "a substituted or unsubstituted arylthio" (see claim 1, line 10), which appears to be the same group as intended by -S-(substituted or unsubstituted aryl). It is, however, encouraged that consistent terminology be used to through out the claims.
2. In claim 11, it is recited that "L is -NHSO₂R-, or -NHC(O)R-; wherein **R** is an **acyl** group, ..." and the specification at page 23 provides that:

An acyl group, as used herein, is an -C(O)NR_xR_z, -C(O)OR_x, -C(O)R_x, in which R_x and R_z are each, independently, -H, a substituted or unsubstituted aliphatic group or a substituted or unsubstituted aromatic group.

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As can be seen from the definition of 'an acyl group' appears to represent a monovalent group and the claim does not clearly set forth that the recited groups: $\text{-NHSO}_2\text{R-}$ and -NHC(O)R- are bivalent such that they fit in the definition of the linking group L. The specification does not provide any explanation or examples wherein, for example, when L is $\text{-NHSO}_2\text{R-}$ and R is an acyl group, etc.

3. Claim 48 recites the limitation "L is $\text{-NHSO}_2\text{CH}_2\text{-}$, $\text{-NHC(O)CH}_2\text{-}$, or $\text{-NHSO}_2\text{CH=CH-}$ " in lines 1-2. There is insufficient antecedent basis for this limitation in claim 1 on which claim 48 is dependent. The definition of L in claim 1 does not include the above recited groups.
4. Claim 49 does not further limit claim 1.
5. Claim 50 recites the limitation "L is $\text{-CH}_2\text{N(R)-}$; -CH(NR)- ; $\text{-NHC(O)R}_{130}\text{-}$; .. $\text{-NHSO}_2\text{R}_{130}\text{-}$;" in lines 1-5. There is insufficient antecedent basis for this limitation in claim 1 on which claim 50 is dependent. The definition of L in claim 1 does not include the above recited groups.

Duplicate Claims

Applicant is advised that should claim 1 be found allowable, claim 49 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 49 does not further limit claim 1.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**/Deepak Rao/
Primary Examiner
Art Unit 1624**

April 28, 2009